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Docket No. 2026-4302US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): YANAGI et al

Group Art Unit: TBA

Int. Serial No.: PCT/US00/15446

Examiner: TBA

Int. Date: 02/06/00

For: CLONED GENOME OF INFECTIOUS HEPATITIS C VIRUS OF GENOTYPE 2A AND
USES THEREOF

INFORMATION DISCLOSURE STATEMENT

ASSISTANT COMMISSIONER OF PATENTS

POB 2327

Arlington, VA 22202 3513

Attn: Box PCT

Sir:

This Information Disclosure Statement is filed in accordance with 37 C.F.R. §§1.56, 1.97 and 1.98. The items listed on Form PTO-1449, a copy of which is enclosed, are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

1. ☐ For each of the following items listed on the enclosed copy of Form PTO-1499 that is not in the English language, an English language translation of that item or a portion thereof is enclosed.
2. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. ☐ Any copy of the items listed on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in application Serial No. _____, filed _____.

4. ☒ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
- ☐ 37 C.F.R. §1.97(b)(1), within three months of the filing date of a national application other than a CPA; or
 - ☒ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application; or
 - ☐ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits; or
 - ☐ 37 C.F.R. §1.97(b)(4) before the mailing date of a first office action after the filing of an RCE under §1.114.
5. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.
6. ☐ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):
- ☐ A check in the amount of \$180.00 is enclosed in payment of the fee.
 - ☐ Charge the fee to Deposit Account No. 13-4500, Order No. _____. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.
7. ☐ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:
- a. one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
 - b. the fee due under 37 C.F.R. §1.17(p) which is paid as set forth in paragraph 11 below.

8. ☐ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
- a. ☐ 37 C.F.R. §1.313(b)(3) or §1.313(c)(1), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue and fee pursuant to 37 C.F.R. §1.17(h);
 - b. ☐ 37 C.F.R. §1.313(c)(2) or §1.313(c)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Request for Continued Examination (RCE) or a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue and fee pursuant to 37 C.F.R. §1.17(h).
 - c. ☐ The fees due under 37 C.F.R. §§1.17(h) and 1.17(p) are paid as set forth in paragraph 10 below.
9. ☐ I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- ☐ I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
10. ☒ This document is accompanied by ☒ a Search Report ☐ Communication which was cited in a corresponding PCT Application No.: PCT/US00/15446 or ☐ Foreign counterpart application
11. ☐ A check in the amount of \$ _____ is enclosed in payment of the fees due under 37 C.F.R. §§1.17(h) and 1.17(p).
- ☐ Charge the fees due under 37 C.F.R. §§1.17(h) and 1.17(p) to Deposit Account No. 13-4500, Order No. _____. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.
12. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 13-4500, Order No. 2026-4302US. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

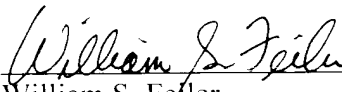
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Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: December 3, 2001

By:



William S. Feller

Registration No. 26,728

Correspondence Address:

MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, NY 10154-0053
(212) 758-4800 Telephone
(212) 751-6849 Facsimile

FORM PTO-1449 INFORMATION DISCLOSURE CITATION	Attorney Docket: 2026-4302	Serial No.: PCT/US00/15446
	Applicant: Yanagi, et al.	
	Filing Date: 06 February 2000 (06. 02. 00)	Group Art Unit: TBA

U.S. PATENT DOCUMENTS							
Examiner Initial		Patent Number	Issue Date	Name	Class	Sub-Class	Filing Date

FOREIGN PATENT DOCUMENTS							
Examiner Initial		Patent Number	Publication Date	Country	Class	Sub-Class	Translation
		EP 0532 167	March 17, 1993	EPO			<input type="checkbox"/> Yes <input type="checkbox"/> No
		WO 91/15575	October 17, 1991	PCT			<input type="checkbox"/> Yes <input type="checkbox"/> No
		WO 00/26418	May 11, 2000	PCT			<input type="checkbox"/> Yes <input type="checkbox"/> No
							<input type="checkbox"/> Yes <input type="checkbox"/> No
							<input type="checkbox"/> Yes <input type="checkbox"/> No

OTHER DOCUMENTS (Including Author, Title, Date, etc.)	
	Okamoto, H. et al, "Nucleotide sequence of genomic RNA of hepatitis C virus isolated from a human carrier: comparison with reported isolates for conserved and divergent region." Journal of General Virology, 72 (pgs 2697-2704) 1991
	Han J. H. et al, " Group specific sequences and conserved secondary structure at the 3' end of HCV genome and its implication for viral replication." Nucleic Acids Research, Oxford University Press, 20:13. (pg 3520) April 1992
	Yanagi, M. et al, "Transcripts of a chimeric cDNA clone of Hepatitis C virus genotype 1b are infectious in vivo." Virology 244 (pgs 161-172) 1998
	Ohno, T. et al, "New hepatitis C virus (HCV) genotyping system that allows for identification of HCV genotypes 1a, 1b, 2a, 2b, 3a, 3b, 4, 5a, and 6a." Journal of Clinical Microbiology 35:1 (pgs 201-207) 1997
	Hashimoto, M. et al, "Typing six major hepatitis C virus genotypes by polymerase chain reaction using primers derived from nucleotide sequences of the NS5 region." International Hepatology Communications 4:5 (pgs 263-267) 1996
	Yong Yuan Zhang et al, "Greater diversity of hepatitis C virus genotypes found in Hong Kong than in Mainland China." Journal of Clinical Microbiology 33:11 (pgs 2931-2934) 1995
	Fox, S. et al, "Rapid genotyping of hepatitis C virus isolates by dideoxy fingerprinting." Journal of Virology Methods 53:1 (pgs 1-9) May 1995

Examiner	Date Considered
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP §609.
 Draw line through citation if not in conformance and not considered.
 Include copy of this form with next communication to Applicant.

OTHER DOCUMENTS (Including Author, Title, Date, etc.)

DEC 2001

	Yanagi, M. et al, "Hepatitis C Virus: An infectious molecular clone of a second major genotype (2a) and lack of viability of intertypic 1a and 2a chimeras." <i>Virology</i> 262 (pgs 250-263) 1999
	De Francesco, R. et al, "A zinc binding site in viral serine proteinases." <i>Biochemistry</i> 35:41 (pgs 13282-13287) 1996
	Stempniak, M. et al, "The NS3 proteinase domain of hepatitis C virus is a zinc-containing enzyme." <i>Journal of Virology</i> 71:4 (pgs 2881-2886) 1997
	Park, Y.M. et al, "Monitoring antibody titers to recombinant core-NS3 fusion polypeptide is useful for evaluating hepatitis C virus infection and responses to interferon-alpha therapy." <i>J. Korean Medicine Sci.</i> 14 (pgs 165-170) April 1999
	Mison, L.M. et al, "Prevalence of hepatitis C virus and genotype distribution in an Australian volunteer blood donor population." <i>Transfusion</i> 37 (pgs 73-78) January 1997
	Wright-Minogue, J. et al, "Cross-genotypic interaction between hepatitis C virus NS3 protease domains and NS4A cofactors." <i>Journal of Hepatology</i> 32:3 (pgs 497-504) 2000
	Martin, J. et al, "In vitro effect of amantadine and interferon. alpha- 2a on hepatitis C virus makers in cultured peripheral blood mononuclear cells from hepatitis C virus-infected patients." <i>Antiviral Research</i> 42:1 (pgs 59-70) 1999
	Urushihara, A. et al, "Changes in antibody titers to hepatitis C virus following interferon therapy for chronic infection." <i>Journal of Medical Virology</i> 42:4 (pgs 348-356) 1994
	Sali, D.L. et al, "Serine protease of Hepatitis C virus expressed in insect cells as the NS3/4A complex." <i>Biochemistry</i> 37:10 (pgs 3392-3401) 1998
	Calvo, P.L. et al, "Hepatitis C virus heteroduplex tracking assay for genotype determination reveals diverging Genotype 2 isolates in Italian hemodialysis patients." <i>J. of Clinical Microbiology</i> 36:1 (pgs 227-233) January 1998
	Bukh, J. et al, "At least 12 genotypes of hepatitis C virus predicted by sequence analysis of the putative E1 gene of isolates collected worldwide." <i>Proceedings of the NAS of the USA, US, NAS 90</i> (pgs 8234-8238) September 1994
	Simmonds, P. et al, "Identification of genotypes of hepatitis C virus by sequence comparisons in the core, E1 and NS-5 regions." <i>J. of General Virology</i> 75 (pgs 1053-1061) 1994
	Van Doorn, L.J. et al, "Sequence analysis of hepatitis C virus genotypes 1 to 5 reveals multiple novel subtypes in the Benelux countries." <i>J. of General Virology</i> 76 (pgs 1871-1876) 1995
	Chaodong, Wu et al, "Antibody response to E2 glycoprotein induced in mice by immunization with plasmid DNA containing sequence derived from a chinese genotype III/2a isolate of hepatitis C virus." <i>Chinese Medical Journal</i> 112:2 (pgs 166-168) February 1999
	Yuki, N. et al, "Quantitative analysis of antibody to Hepatitis C virus Envelope 2 Glycoprotein in patients with chronic Hepatitis C virus infection." <i>Hepatology</i> 23:5 (pgs 947-952) May 1996
	Longombardo, G. et al, "Immune response to an epitope of the NS4 protein of Hepatitis C virus in HCV-related disorders
	Fabrizi, F. et al, "Hepatitis C virus genotypes in chronic dialysis patients." <i>Nephrol. Dial. Transplant.</i> 11 (pgs 679-683) 1996
	Lin, H-H. et al, "Serotypes, genotypes and levels of Hepatitis C Viremia in pregnant women in Taiwan." <i>J. Formos. Medl. Assoc.</i> 95:6 (pgs 429-434) 1996
	Devesa, M. et al, "Reduced antibody reactivity to Hepatitis C virus antigen in Hemodialysis patients coinfectd with hepatitis B virus." <i>Clinical and Diagnostic Laboratory Immunology</i> 4:6 (pgs 639-642) November 1997
	Yuki, N. et al, "Hepatitis C virus replicative levels and efficiency of genotyping by specific PCR and antibody assay." <i>J. of Clinical Microbiology</i> 35:5 (pgs 1184-1189) May 1997
	Zhang, Z-X. et al, "Evaluation of the multiple peptide assay for typing of antibodies to the Hepatitis C Virus: Relation to genomic typing by the Polymerase Chain Reaction." <i>J. of Medical Virology</i> 45 (pgs 50-55) 1995
	Nomura, H. et al, "Interferon therapy and Hepatitis C virus." <i>Journal of Gastroenterology and Hepatology</i> 14:1 (pgs 85-89) January 1999

Examiner

Date Considered

EXAMINER. Initial if reference considered, whether or not citation is in conformance with MPEP §609
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OTHER DOCUMENTS (Including Author, Title, Date, etc.)	
	Furusyo, N. et al, "Differences between interferon-alpha and -beta treatment for patients with chronic hepatitis C virus infection." Digestive Diseases and Sciences 44:3 (pgs 608-617) March 1999
	Yao, G.B. et al, "Long-term efficacy of recombinant interferon alpha 2a in the treatment of chronic Hepatitis C: A randomized prospective study comparing two dose schedules in Chinese patients." Hepato-Gastroenterology 46 (pgs 1059-1064) April 1999
	Martinot-Peignoux, M et al, "Predictors of sustained response to alpha interferon therapy in chronic hepatitis C." Journal of Hepatology 29:2 (pgs 214-223) August 1998
	Lee, W.M., "Therapy of Hepatitis C: Interferon Alfa-2a trials." Hepatology 26 (pgs 89S-95S) 1997
	Linsay, K.L., "Therapy of Hepatitis C: Overview" Hepatology 26 (pgs 71S-77S) 1997
	Marakami, T. et al, "Mutations in Nonstructural protein 5A gene and response to interferon in Hepatitis C virus genotype 2 infection." Hepatology 30 (pgs1045-1053) October 1999
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